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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314		

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
11/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/076,416

Applicant(s)

RIEPING ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25-28,33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25-28,33 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/987,541.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1]** Claims 23, 25-28, 33, and 35-42 are pending in the application.
- [2]** Applicant's amendment to the claims, filed on 9/10/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Receipt of a terminal disclaimer, filed on 9/10/07, is acknowledged.
- [4]** Applicant's arguments filed on 9/10/07 in response to the non-final Office action mailed on 5/8/07 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, First Paragraph

- [6]** The written description rejection of claims 23, 25-28, 33, and 39-42 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (5/8/07 Office action, paragraph 8, beginning at p. 6) and the reasons stated below. The rejection was fully explained in prior Office actions.

RESPONSE TO ARGUMENT: Applicant argues "The aspect of PCR amplification is not present in the claims" and "The gene prior to inactivation is defined

Art Unit: 1656

according to the coding sequence that codes for the specific protein sequence described in the specification, i.e., SEQ ID NO:2.”

Applicant's argument is not found persuasive. To the extent the rejection relied upon the description of the genus of *poxB* genes prior to inactivation, the rejection is withdrawn in view of the claim amendment. However, the rejection is maintained because, as noted in the prior Office action and undisputed by applicant, there is no relationship between inactivating the *poxB* gene by the recited methods, i.e., deletion mutagenesis, insertional mutagenesis, and transition or transversion mutagenesis, and the resulting functional effect(s) on pyruvate oxidase catalytic activity. The Courts generally accept as fact an examiner's finding that is undisputed by applicant. See *In re Kunzmann*, 140 USPQ 235 (CCPA 1964).

While applicant has previously argued “[t]he requirement that *poxB* gene is inactivated clearly means that the polypeptide is not functional” (prior response at p. 8, bottom), there is no such requirement in the claim and the claims have not been so narrowly interpreted. In this case, the phrase “inactivated *poxB* gene” has been interpreted as meaning a gene that is inactive with respect to encoding a full length *poxB* polypeptide. However, the “inactivated *poxB* gene” does not exclude altered genes that encode *poxB* substitution or deletion mutants.

Given the lack of description of a representative number of species of modified *Escherichia* microorganisms, particularly with respect to the unlimited functional effect(s) of inactivating the *poxB* gene, the specification fails to sufficiently describe the

Art Unit: 1656

claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

In the interest of advancing prosecution, it is noted that inserting a limitation that provides a functional effect of the "inactivated poxB gene", e.g., "wherein the modified *Escherichia* microorganism with an inactivated poxB gene has reduced or eliminated pyruvate oxidase catalytic activity as compared to an unmodified *Escherichia* microorganism", would appear to overcome the instant rejection. The suggested limitation finds descriptive support in the specification at p. 6, third paragraph.

[7] The scope of enablement rejection of claims 23, 25-28, 33, and 39-42 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (5/8/07 Office action, paragraph 9, beginning at p. 9) and the reasons stated below. The rejection was fully explained in prior Office actions.

RESPONSE TO ARGUMENT: Applicant argues "The aspect of PCR amplification is not present in the claims" and "The gene prior to inactivation is defined according to the coding sequence that codes for the specific protein sequence described in the specification, i.e., SEQ ID NO:2."

Applicant's argument is not found persuasive. To the extent the rejection relied upon the description of the genus of poxB genes prior to inactivation, the rejection is withdrawn in view of the claim amendment. However, the rejection is maintained because, as noted in the prior Office action and undisputed by applicant, there is no structure-function relationship between the recited inactivated poxB gene and the

Art Unit: 1656

function of reducing or eliminating pyruvate oxidase catalytic activity. The Courts generally accept as fact an examiner's finding that is undisputed by applicant. See *In re Kunzmann*, 140 USPQ 235 (CCPA 1964).

While applicant has previously argued "[t]he requirement that poxB gene is inactivated clearly means that the polypeptide is not functional" (prior response at p. 8, bottom), there is no such requirement in the claim and the claims have not been so narrowly interpreted. In this case, the phrase "inactivated poxB gene" has been interpreted as meaning a gene that is inactive with respect to encoding a full length poxB polypeptide. However, the "inactivated poxB gene" does not exclude altered genes that encode poxB substitution or deletion mutants.

In the interest of advancing prosecution, it is noted that inserting a limitation that provides a functional effect of the "inactivated poxB gene", e.g., "wherein the modified *Escherichia* microorganism with an inactivated poxB gene has reduced or eliminated pyruvate oxidase catalytic activity as compared to an unmodified *Escherichia* microorganism", would appear to overcome the instant rejection. The suggested limitation finds descriptive support in the specification at p. 6, third paragraph.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the amount of experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the

Art Unit: 1656

claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - Double Patenting

[8] The provisional obviousness-type double patenting rejection is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in the prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the application in rejection parts [c], [h], [o], [q], [w], and [z] are abandoned and [y] has issued as US Patent 7,052,883 and a terminal disclaimer has been filed. Applicant requests the remaining provisional rejections be held in abeyance with respect to the remaining applications.

Applicants' argument is not found persuasive. The rejection as it applied to application 10/114,703, now issued as US Patent 7,052,883 (identified as [y] in the Office action mailed on 10/19/05) is withdrawn in view of the submission of a terminal disclaimer.

As to the remaining co-pending applications that are not abandoned or issued, the provisional rejection is maintained.

Art Unit: 1656

[9] It is noted that applications 10/481,746 (identified as [m] in the Office action mailed on 10/19/05) and 10/481,745 (identified as [i] in the Office action mailed on 10/19/05) have issued as US Patent 7,712,883 and 7,241,600, respectively. Thus, since these applications have issued as patents, the rejections are no longer provisional.

[10] The examiner reminds applicant that an earnest attempt has been made to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, e.g., cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Requirements for Deposit of Biological Material

[11] It is noted that claims 35-38 are drawn to microorganisms. It appears applicant has complied with the requirements for deposit of biological material in view of the remarks filed on 7/20/04 at p. 8, top.

Conclusion

[12] Status of the claims:

Claims 23, 25-28, 33, and 35-42 are pending.

Claims 23, 25-28, 33, and 39-42 are rejected.

Claims 35-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656